

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effects of Flaxseed oil supplementation on inflammatory markers in overweight pre-diabetes patients

Protocol summary

Study aim

Determine the effect of flax seed oil supplement on inflammatory indexes in overweight pre-diabetes patients

Design

In this study, 80 pre-diabetic and eligible patients who are referred to the Isfahan Cardiovascular Center are selected. Participants are randomly divided into two intervention and control groups and each participant is given an assigned code.

Settings and conduct

This is a double-blind, randomized controlled clinical trial of overweight pre-diabetic individuals referred to the Isfahan Cardiovascular Center. At the beginning of the study, general information questionnaire including age, height, weight, occupation, history of disease, type and dosage of consumable drugs are completed. Then, the subjects were randomly divided into two groups and consumed flaxseed oil (1 g, 2 times a day) and placebo (1 g, 2 times a day) for 14 weeks. Serum samples of the participants in the study were collected at the beginning and the end of the study by blood sampling and centrifugation. At the end of the study, was used to measure hs-CRP and TNF α . Participants will receive special codes for the control and intervention group that the investigator and the participants do not know about the type of intervention of each individual.

Participants/Inclusion and exclusion criteria

The inclusion criteria included people with impaired fasting glucose, fasting blood sugar of between 100 and 125 mg / dl, and body mass index of between 25 and 29/9. Exit criteria From the study included Receiving oral hypoglycaemic drugs (sulfonylurea, magnetlonid, bialuanides, thiazolidinedione, alpha-glucosidase inhibitors, DPP-4 inhibitors, SGLT2 inhibitors and insulin injections, any type of acute and chronic disease other than impaired glucose tolerance which affect on The metabolism of glucose or uncontrolled, any kind of susceptibility or intolerance to flaxseed oil, smoking,

having severe activity, and an unusual diet (more than 150 minutes of moderate aerobic activity per week or 75 minutes of aerobic activity with intensity Highly in the week, removing one or more food groups from the daily diet), women with Having a monthly cycle for at least the past 6 months, using basic anti-inflammatory drugs (steroidal and non-steroidal anti-inflammatory drugs), consuming regularly, flaxseed or fish oil supplements (one-time use or more per week for a fixed dose), and The consumption of fish is more than 340 grams per week and soy consumption is fixed at once or more than once a week

Intervention groups

The subjects in the intervention group will receive flaxseed oil supplement (two 1000-mg capsules per day, Barij Essence Co., Kashan) for 14 weeks. On the other hand, the subjects in the control group will take a placebo similar to the compound of the other group, which contained oral paraffin (two 1000-mg capsules per day).

Main outcome variables

TNF α ; hs-CRP

General information

Reason for update

Acronym

YDS

IRCT registration information

IRCT registration number: **IRCT20120913010826N26**

Registration date: **2018-02-05, 1396/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-05, 1396/11/16**

Update count: **0**

Registration date

2018-02-05, 1396/11/16

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

azadnajarzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Flaxseed oil supplementation on inflammatory markers in overweight pre-diabetes patients

Public title

The effect of Flaxseed oil on pre-diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The body mass index is between 25 and 29.9. Fasting blood sugar is greater than or equal to 100 and less than 126 mg / dL.

Exclusion criteria:

Receive oral hypoglycemic drugs and insulin injections. Cure for any type of acute and chronic disease other than impaired glucose tolerance. Any kind of allergy or intolerance to Linseed oil Smoking Having severe activity and unusual diet Women having a monthly cycle for at least 6 months Use of anti-inflammatory drugs Having regular consumption of your seed, Flaxseed oil or Fish oil supplements Pregnancy and lactation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the randomized code obtained from the computer

Blinding (investigator's opinion)

Double blinded

Blinding description

No external person was involved in the preparation of a randomized list, nor in the counting and packaging of capsules. All participants in this study (patients, health care provider) were unaware of the outcome of the treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Shahid Sadoughi University of Medical Sciences

Street address

Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2016-10-22, 1395/08/01

Ethics committee reference number

ir.ccu.sph.rec.1395.118

Health conditions studied

1

Description of health condition studied

Pre-diabetes

ICD-10 code

R73.02

ICD-10 code description

Impaired glucose tolerance (oral)

Primary outcomes

1

Description

Crp

Timepoint

Before the intervention and 14 weeks after the

intervention
Method of measurement
Blood test.mg/l

2

Description
TNF α
Timepoint
Before the intervention and the end of the week 14
Method of measurement
Blood test.Pgr/ml

Secondary outcomes

1

Description
Fbs
Timepoint
Before the intervention and the end of the week 14
Method of measurement
Blood test. mg/dl

2

Description
Weight
Timepoint
Before the intervention and the end of the week 14
Method of measurement
Balance, kg

Intervention groups

1

Description
To the intervention group, for 2 weeks, 2 capsules of 1000 mg of linseed oil will be given to the Barij Essen Pharmaceutical Company in Kashan. Given the length of the study, 196 capsules are for each person
Category
Prevention

2

Description
To placebo recipients, during the same periodic study, a placebo will be given to the recipient of the supplementation of flaxseed oil containing oral paraffin from the pharmaceutical company Barij Essen in Kashan. Given the length of the study, 196 capsu
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Jinan Diabetes Charity Association
Full name of responsible person
Aghaie
Street address
Danesh Ave, Shariati St., Najaf Abad, Isfahan
City
Najaf Abad
Province
Isfahan
Postal code
85137-94791
Email
janan.ansar@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences Yazd
Full name of responsible person
Dr. Azadeh Najarzadeh
Street address
Sadoughi University of Medical Sciences, shahid bahonar sq,Yazd
City
Yazd
Province
Yazd
Postal code
8915173160
Email
azadehnajarzadeh@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi University of Medical Sciences Yazd
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Azadeh Nadjarzadeh
Position

Associate Professor, nutrition specialist

Latest degree

Ph.D.

Other areas of specialty/work

Street address

Department of nutrition, school of public health,
shahid sadoughi university of medical sciences, Yazd,
Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35382091001

Fax

Email

azadnajarzadeh@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Azadeh Nadjarzadeh

Position

Associate Professor, nutrition specialist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of nutrition, school of public
health,shahid sadoughi university of medical
sciences, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35314921010

Fax

Email

azadehnajarzadeh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Azadeh Nadjarzadeh

Position

Associate Professor, nutrition specialist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of nutrition, school of public
health,shahid sadoughi university of medical
sciences, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 353820910014

Fax

Email

azadnajarzadeh@ssu.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data report will be shared after publishing the paper.

When the data will become available and for how long

Six months after publish

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Using for Meta-analysis

From where data/document is obtainable

Center nutrition, public health, univercity of medical
scienicies yazd Tel: 009835 31492239 Email:
azadehnajarzadeh@gmail.com Azadenadjarzadeh

What processes are involved for a request to access data/document

It will be sent two weeks after the receipt of the email
with the consent of the co-workers.

Comments